The introduction of the Unified Patent Court (UPC) in Europe presents concerns and opportunities to the life sciences industry. Those concerns and opportunities during the transitional period are those of more instant relevance and so we discuss those in detail, with the questions posed by the end of the transitional period being briefly considered towards the end.

Opting-out

For patentees, the first question to be resolved is the use of the opt-out provision; more broadly, do I want to play in the new system and, if so, when? Given that life sciences patents tend to protect the income stream on a product, either alone or in combination with a limited number of additional patents, they are individually valuable assets. That may be the key factor in determining whether to place them at risk in the UPC. An assumption in the following is that the cost of opting out and/or withdrawing an opt-out are not prohibitive.

The advantages offered by the new system are less keenly felt by the life sciences patentee than for most other industries: the cost of litigating in a number of jurisdictions is less of an issue given the values in dispute; divergent decisions on the same patent family from the national courts (while not ideal) do offer a valuable middle ground between the binary outcome of a single decision; litigation may still be necessary in those states not yet participating, nor allowed to participate, in the UPC and, so long as interim measures are in place, delay in coming to a trial on the merits is more acceptable.

During the transitional period, the risk to the patentees in not opting-out comes in the initiation of revocation and/or decla-
rations of non-infringement actions by putative infringers. Whilst the latter may well result in an infringement action being started by the patentee in the division of his choice, depending on whether the patentee has sufficient basis to allege a threat to infringe and/or the benefits perceived to be derived from the different divisions, the patentee can still lose big from a single decision against it: the UPC will be a court with no case law and brand new procedures and it can decide the fate of a patent in one decision for all participating states.

Previously, it had been contemplated that a patentee could always opt-out, as long as national proceedings were underway, and withdraw that opt-out before commencing in the UPC. That is, if the UPC looks to offer the patentee an advantage, he can opportunistically withdraw his opt-out and commence an action before the UPC. The latest version of the Rules of Procedure modifies that position somewhat – withdrawal is not permitted if the patent has ever been subject to national proceedings – and that may create opportunities for alleged infringers to lock opt-out patents out of the system. Accordingly, there is some risk associated with opting out.

A key issue for the industry is that the existing courts are more of a known quantity. Until the UPC has built up a track record, it is likely that most life sciences patentees will seriously consider the opt-out. The difficulty in adopting an all-out approach as an industry comes at the end of the transitional period. At that point, having a mandatory court system for European patents that has not had experience of dealing with life sciences cases may be a problem. A desire to see the new court gain experience and to influence the direction of the case law may see the withdrawal of an opt-out being used more often than otherwise.

For putative infringers, the opt-out provisions offered more limited options: first, whether to seek to commence a revocation action in advance of a patentee getting his house in order (the sunrise period ought to afford the patentee sufficient protection in this regard, but no doubt mistakes will happen); second, whether to commence proceedings earlier than otherwise in a national court to lock out an opt-out patent. Equally, the possibility of central revocation may play into opposition strategies, but not to any great extent until the transitional period has expired (considered below); and third, whether there is any advantage in locking a patentee into the system by starting an action early under the new rules to create the possibility of bringing a central revocation action later when commercial certainty around a potential product is greater.

When might the new system offer an advantage?

The test for and timing of an interim injunction

Life sciences pharmaceutical patentees commonly seek preliminary or interim relief from the national courts and injunctions are the most important of the measures sought. ‘The current national systems differ in relation to the requirements to be met – when does a sufficient threat exist (inclusion on pricing lists, having a marketing authorisation, etc)? What degree of urgency is required having learned of the alleged infringement? How strong does the case on the merits need to be (has the patent been forged by fire)? What about the balance of convenience or justice factors?’

Article 62 of the UPC Agreement provides that the Court may grant injunctions ‘intended to prevent any imminent infringement, to prohibit, on a provisional basis and subject, where appropriate, to a recurring penalty payment, the continuation of the alleged infringement or to make such continuation subject to the lodging of guarantees intended to ensure the compensation of the right holder’. The Court has discretion ‘to weigh up the interests of the parties’ including the potential harm and may require the patent holder to provide evidence that its right ‘is being infringed, or that such infringement is imminent’. Rule 211 of the current draft of the rules of procedure provides some further clarity.

One reading of the UPC Agreement, particularly as supplemented by the rules, would suggest that the requirements from all of the national courts are being cumulatively imposed in the new system. That is unlikely to be the practice – the long list is more likely a result of a political compromise in the drafting process. The UPC will almost certainly offer a test that differs from that applied in some (or all) national courts. On occasion that test may be more advantageous to the patentee. A further factor in the mix is that the various divisions of the UPC may not all apply the same requirements in deciding on the grant of interim injunctions – the rules are written in a permissive way with most factors being optional. To the extent that local variations exist, then the UPC will offer a range of venues for seeking interim relief and patentees will, accordingly, shop around the venues.

The potential cost of a wrongly granted interim injunction

Another question in relation to interim injunction within the UPC is the scope of liability, if any: if the interim injunction was wrongly granted, who can claim and for what? This issue may

Are we likely to see cases in the central division?

For the reasons discussed already, it is likely that a significant number of life sciences patents will be opted-out, at least during the early years of the new system. On one view, that would suggest that the number of cases capable of being started in the central division (declarations of non-infringement, non-EU domiciled infringement actions and revocation proceedings) will be low. For those within the system, or those where the opt-out may be withdrawn, the patentee will normally have a choice as to the division in which to bring an infringement action. Long-term, patentees are likely to seek the division which has relevant experience and expertise. That could be the central division given that a specific branch of the central division will exist for life sciences cases in London. Equally, each division’s approach to the issues highlighted above (to the extent that those differ between divisions) is likely to be an important factor in choosing where to commence proceedings.
Supplementary protection certificates (SPCs) play a major role in the protection of medicinal products. SPCs are national (not sui generis) exclusivity rights issued by the national industrial property offices to compensate the patentee for regulatory product approval delay and consequential loss of the period of exclusivity granted by a basic patent. SPCs extend the protection offered by the basic patent for the approved product for a period of up to five years (and six months in case of a paediatric extension). SPCs for medicinal products are regulated by the SPC Regulation 469/2009 and national procedural law.

The UPC Agreement and the Rules of Procedure provide for the exclusive competence of the UPC in respect of infringement and invalidity actions for SPCs (after the transitional period).

Article 3(b) of the UPC Agreement provides that the UPC Agreement shall apply to any SPC issued for a product protected by a patent. Article 30 provides that a SPC shall confer the same rights as conferred by a patent and shall be subject to the same limitations and the same obligations and Article 32(1) provides that the UPC shall have exclusive competence in respect of infringement and invalidity actions in respect of SPCs. Rule 2 of the Rules of Procedure provides further clarity.

The UPC Agreement and the Rules of Procedure contemplate the possibility of “unitary” SPCs. However, at present a single unitary SPC issued on the basis of a Unitary Patent with the same single unitary territorial scope is not possible. Under Article 9(1) of the SPC Regulation, SPCs are national (not single unitary) rights issued by the respective national industrial property offices (not a single unitary granting office such as the EPO). The UP Regulation and UPC Agreement and Rules of Procedure do not set aside or amend Article 9(1) of the SPC Regulation. It is clear, therefore, that single unitary SPCs based on Unitary Patents are not possible at present and require an amendment of European legislation to allow for such unitary SPCs.

Equally, national SPCs granted by national IP offices on the basis of a Unitary Patent are not possible within the current SPC Regulation. The definition of basic patent in the SPC Regulation would arguably encompass Unitary Patents. However, the UPC Regulation would still need to be amended to allow for the grant of national SPCs on the basis of a Unitary Patent by the national IP offices.

The UPC Agreement and the Rules of Procedure provide that the UPC shall have exclusive competence in respect of infringement and invalidity actions in respect of SPCs. National SPCs issued on the basis of European patents shall be subject to this exclusive competence, albeit that Articles 15(2) and 16(2) and Article 18 of the SPC Regulation provide for non-UPC competence for designated actions and appeals. The owner of a European patent can apply to opt-out of the exclusive competence of the UPC during the transitional period and such opt-out would automatically extend to the SPC based on the opted-out patent.

The owner of a European patent (including a European patent that has expired) can apply to opt-out of the competence of the UPC.

Once a patent has been opted-out, the opt-out can be withdrawn and the patent can be opted back in at any time before the end of the transitional period, provided no action has been commenced before a national court. An application to opt-out or withdraw the opt-out automatically extends to the SPC based on the opted-out patent (Rule 5.2(a) of the Rules of Procedure).

Where an SPC is granted before lodging the application to opt-out, the holder of the SPC shall – if different from the proprietor(s) of the patent – lodge the application to opt-out together with the proprietor(s) of the patent (Rule 5.2(b) of the Rules of Procedure).

Where any such SPC is granted subsequent to lodging the application to opt-out, the opt-out shall take effect automatically on grant of the SPC (Rule 5.2(c) of the Rules of Procedure).

It is not possible to opt-out SPCs based on Unitary Patents (Rule 5.2(e) of the Rules of Procedure). It is clear from the Rules of Procedure that an SPC based on a Unitary Patent cannot be opted-out. However, it is unclear how the European legislation will be amended to allow for the grant of SPCs based on Unitary Patents and whether the UPC system and the SPC Regulation will be amended to allow for the grant of unitary SPCs based on Unitary Patents or the grant of a bundle of national SPCs based on Unitary Patents.

The second alternative would require fewer amendments to the European legislation, but even an amendment to allow for national SPCs based on Unitary Patents would involve complex legal and practical issues.

On the other hand, if the UPC offers no protection to third parties from the granting of an interim injunction, that may be more advantageous than some of the national courts.

The introduction of an early resolution mechanism

There are growing calls within the innovator biopharmaceutical sector for some form of early resolution mechanism to be introduced. One example is the proposal by EFPIA for applications for generic authorisation to include the...
provision of the generic applicant’s regulatory dossier to the relevant patentees/licensees at the time of marketing authorisation application. The proposal is that there is a corresponding obligation on the patentee to commence proceedings for any infringement in good time so that issues are resolved before the generic launch. The introduction of such a mechanism is unlikely to garner industry-wide support at present and is unlikely to materialise in the short term. That said, it may be a useful incentive in due course if the UPC system has not managed to attract life sciences patentees and is looking to do so.

When can I seek a declaration of non-infringement?

Another area of divergence for national courts is the requirements for seeking a declaration of non-infringement. The introduction of the UPC allows potential (non-)infringers to seek comfort centrally. The requirements to engage the declaratory jurisdiction differ from the current national rules. Rule 60 of the current draft of the rules of procedure provides that “a declaration that the performance of a specific act does not, or a proposed act would not, constitute an infringement of a patent may be made by the Court” if the applicant for the declaration has applied to the patent owner or licensee, and has not received a response within one month. This looks to be similar to the UK position, save for the moratorium period of one month. In effect it provides a broad jurisdiction to hear matters at the time chosen by the putative non-infringer. It differs from current national laws (in for example, Spain, Germany, Italy and France) that have, to varying degrees, a requirement for the party seeking a declaration to have carried out serious and effective preparations for the acts in question. Again, how the UPC provision will work out in practice, including the ability of patentees to sue for infringement in a division of their choice (under Rule 70), may well be a factor considered by patentees in deciding whether to opt-out of the current system.

Are the exceptions to infringement different?

An area where the UPC will offer a different choice for patentees is the extent of the research exemption and Bolar provisions. Article 27 of the UPC Agreement provides that the rights conferred by a patent shall not extend to “acts done for experimental purposes relating to the subject matter of the patented invention” or “the acts allowed pursuant to Article 13(6) of Directive 2001/82/EC or Article 10(6) of Directive 2001/83/EC in respect of any patent covering the product within the meaning of either of those Directives”.

At present national law provides a spectrum as to the acts encompassed by these two provisions – encompassing the extent to which clinical trials directed to non-EU marketing applications count, whether the acts must be done solely for experimental purposes, whether health technology assessments are included, whether innovators can rely on the exemption or only generic applicants, whether third party suppliers can benefit from the exemption, and which patents are blessed (is a device patent captured)? Ireland, Spain and the UK have recently broadened their Bolar provisions. The UK amended its law in October 2014 to offer one of the more generous positions (to the potential infringer) and in doing so, sought to amend the provision for acts “done for experimental purposes” rather than the Bolar provision. Part of the rationale was a hope that the national law definition of “acts done for experimental purposes” would be used to inform the definition within the UPC system. How this works in practice will certainly provide patentees with a choice within Europe over the extent of these exceptions to their patented rights.

The post-transition world

The UPC system offers a new choice to potential infringers when considering whether to oppose a patent – a central revocation action. Until the expiry of opt-outs, it is unlikely that the alleged infringer will be able to rely on that possibility (we expect that life sciences patents will largely be opted-out) and so, during the transitional period, opposition strategies are unlikely to be impacted greatly. Once a patentee is fixed into the new system, central revocation becomes a realistic option. It is likely to be more attractive than opposition at the EPO because the potential infringer will have the option of commencing the attack later – nearer to some certainty over his own product launch (and so knowing whether the patent really is a problem he needs to address).

Obtaining evidence to prove your case

Life sciences patentees are often in need of evidence regarding the product and/or process implemented by potential infringers before the product hits the market and becomes publicly available. In addition, there is a demand for information relating to regulatory information on that product or process. The new system is geared up to provide advantages in relation to obtaining the evidence necessary to prove your case throughout the contracting member states.

As indicated by the non-comprehensive list of Article 53 of the UPC Agreement, evidence may be given by any means. The current national systems (save for the common law countries) eschew discovery/disclosure obligations in preference to targeted requests – use of a saisie-contrefaçon, requests for specific documents such as parts of dossiers or inspection of competitor premises.

To the contrary, the UPC offers a large spectrum of listed evidentiary means such as hearing the parties (Rule 112), requests for information (Rule 191), production of documents (Rule 190), hearing witnesses (Rule 178), opinions by experts (Rules 181 and 185), experiments (Rule 201), description and/or physical seizure of evidence (Rule 196), inspection of premises (Rule 199), comparative tests or experiments and affidavits (Rule 175).

Only the need to protect confidential information of the alleged infringer (as generally stated notably at Article 58 of the UPC
To the extent that local variations exist, the UPC will offer a
mencing proceedings and patentees will, accordingly, select
range of venues for efficiently gathering evidence before com-
prior filing with the Court of a protective letter by the defendant
Pre-proceedings evidence preservation could be used alterna-
tively or cum ulatively with the pow er of the Court to order a
motion of evidence at Article 59 of the UPC Agreement.
T hird parties to the litigation including health authorities, cer-
party to disclose specified inform ation w hile a case is pending.
Evidence gathering m eans in the new  system  include
Evidence gathering m eans in the new  system  include
This is because this evidentiary measure is defined as a provi-
sional measure (Article 60(1) of the UPC Agreement), subject to
ister parte proceedings unless it is demonstrated why the de-
fendant should not be heard (Rule 192(3)). Furthermore, even
if an order is rendered ex parte on this evidentiary measure, the
rule will be to order a security for the potential cost of a wrongly
granted order (Rule 196(6)). Additionally, as a provisional 
measure, a request for securing evidence may be blocked by the
prior filing with the Court of a protective letter by the defendant
(combination of Article 60(1) of the Agreement and Rule 207).

To the extent that local variations exist, the UPC will offer a
range of venues for efficiently gathering evidence before comm-
mencing proceedings and patentees will, accordingly, select
the venues.

Pre-proceedings evidence preservation could be used alterna-
tively or cum ulatively with the power of the Court to order a
party to disclose specified information while a case is pending.
The new system will offer such possibility of a forced produc-
tion of evidence at Article 59 of the UPC Agreement.

Third parties to the litigation including health authorities, cert-
ifying bodies or other providers, may be ordered to produce evi-
dence (Rule 190(3)). Patent holders capable of specifying the
evidence they are looking for will notably take advantage of
the fact that if a party fails to comply with an order to produce
evidence, the Court should take that failure into account when
deciding on the issue at stake (Rule 190(7)).

This forced production of evidence could be combined with a
request to communicate such information in the control of that
other party or third party as is specified in Article 67 of the UPC
Agreement (origin, distribution channels, quantities, identity
of other involved parties) or such other information as is rea-
sonably necessary for the purpose of advancing that party’s case
(Rule 191).

The parties and the Court may also optionally request and
order the gathering of expert opinion which may prove helpful
in the life sciences sector.

Interestingly, the Court will also be able to seek evidence on its
own motion (but only after hearing the parties), ordering an
experiment to prove a statement of fact (Rule 201) or issuing
letters rogatory for the hearing of witnesses or experts by other
competent courts or authorities (Rule 202).

The combination of several of these evidence gathering means
to be offered in the UPC could prove more advantageous than
what any national court offers today.

Modify your all-out strategy

The UPC system offers an attractive procedure and will, in
all likelihood, be staffed with experienced judges. Combined
with the efficacy of remedies covering the entirety of the
UPC, we believe that in the long run the combination of ad-
vantages offered by the UPC system will be hard to resist for
life sciences companies. Even if the initial approach is likely
to be an all-emcom passing opt out, the wait and see strategy
is not going to be possible in the long run. Indeed, there may
be substantial long term strategic advantages for owners of life
sciences patents in the UPC that should not be sacrificed in
the interest of what only looks like legal certainty in the first
place, but will come at the cost of continuing hard to predict
and difficult to coordinate outcomes in the various EPC
member states. If the UPC system is able to prove itself also
in the area of life sciences it will need cases to apply its new
tools and procedure to.

We propose, therefore, that life sciences companies take a mod-
ifed approach to the all-out strategy. While some patents con-
sidered to be crown jewels may not be put at stake in the initial
period of the coming into existence of the UPC system, life sci-
ences companies may be able to identify strong patents on
smaller products where the stakes are less high, which may well
be suited to be enforced in the UPC system. We believe, there-
fore, that over time life sciences companies are likely to adopt
an approach where the (presumably) strongest patents are used
within the UPC, whereas secondary patents where validity
(based on past experience) will be more of a challenge, remain
in the old system with no central invalidation after the EPO op-
position phase is over and enforcement on a country-by-coun-
try basis seems more attractive.

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